EXERGEN Temporal Artery Thermometer

Instructions For Use

Quick Check-List:

- Read instructions completely before using
- See www.temporalscanner.com for Educational Video
- Remove protective cap before using
- Reads arterial temperature, which is a core temperature very close to rectal temperature (See pg. 9)
- Sensor should be clean (See pg. 12)
- If perspiration is present see pg. 7

TemporalScanner™ 2000C

Important Safety Instructions

READ ALL INSTRUCTIONS BEFORE USING

When using the product, especially when children are present, basic safety precautions should always be followed, including the following:

- This product is intended for household use only. For information on thermometers for professional use, see www.quickmedical.com, or call 1-888-345-4858.
- Use this product only for its intended use as described in this manual.
- Use of this product is not intended as a substitute for consultation with your physician.
- Do not take temperature over scar tissue, open sores or abrasions.
- Basic safety precautions should always be observed, especially when this product is used by, on or near children or invalids.
- The operating environmental temperature range for this product is 60 to 104°F (15.5 to 40°C).
- Always store this thermometer in a clean, dry place where it will not become excessively cold (-4°F/-20°C), or hot (122°F/50°C).
- The thermometer is not shockproof. Do not drop it or expose it to electrical shocks.
- This thermometer is not intended to be sterile. Do not try to sterilize it. Follow the cleaning instructions as described in this manual.
- Do not use this thermometer if it is not working properly, if it has been exposed to temperature extremes, damaged, been subject to electrical shocks or immersed in water.
- There are no parts that you can service yourself except for the battery, which you should replace when low following the instructions in this manual. For service, examination, repair, or adjustments, return your thermometer to Exergen.
- Do not operate where aerosol spray products are being used or where oxygen is being administered.
- Do not take temperatures with this thermometer near places that are very hot, such as fireplaces and stoves.
- Do not use this thermometer outdoors.
- Never drop or insert any object into any opening.

- If your thermometer will not be used regularly, remove the battery to prevent possible damage due to chemical leakage. If the battery leaks, remove carefully. Do not allow bare skin to touch leaking fluid.
- Dispose of used batteries properly. Do not wrap them in metal or aluminum foil. Wrap them in newspaper before disposing of them. Do not burn them. Battery may explode if overheated.

SAVE THESE INSTRUCTIONS.

Table of Contents

Important Safety Instructions	2
Introduction	3
Before Using, Familiarize Yourself With the Instrument	5
Measuring TA Temperature	6
How to Take a Temperature	8
Clinical Temperature Information	9
Cleaning the Instrument	12
Changing the Battery	13
Display Messages, °C/°F Conversion	14
Product Specifications	15
Warranty	16

Introduction

Congratulations and thank you for purchasing the Exergen TemporalScanner Thermometer for consumer use. Your new TemporalScanner Thermometer is a totally non-invasive system with advanced infrared technology providing maximum ease of use with quick, consistently accurate measurements. Advanced, patented technology measures temperatures with a gentle stroke across the forehead.

The TemporalScanner Thermometer has been clinically tested for accuracy compared to rectal thermometers and temperature sensors inserted in the heart during course of patient treatment[3] and accepted for use in major hospitals, making it the ideal thermometer for use with newborns, infants, children or adults.

The TemporalScanner has patented software, providing arterial heat balance. This unique process determines temperature by accurately measuring the balance between the tissues warming from arterial blood and tissues cooling/ warming caused by heat loss/gain to the environment.

Why take temperature measurements at the skin surface over the temporal artery?

The best place to measure temperature is the center of the heart, but this can be done only under a doctor's supervision. Doctors know that measurement of the blood temperature in a major artery accurately reflects true body temperature. The TemporalScanner Thermometer is designed to measure the temperature of the skin surface over the temporal artery, a major artery of the head.

The temporal artery is connected to the heart via the carotid artery, directly leading from the aorta, the main trunk of the arterial system. It offers constant blood flow. It is the only such artery positioned close enough to the skin surface to provide access needed to take an accurate measurement. It is easy to use because it is ideally located at the front portion of the forehead. The TemporalScanner is easier and gentler to use than other types of measurement devices such as oral, rectal, underarm and in-ear thermometers because it is truly non-invasive.

How does the TemporalScanner Thermometer work?

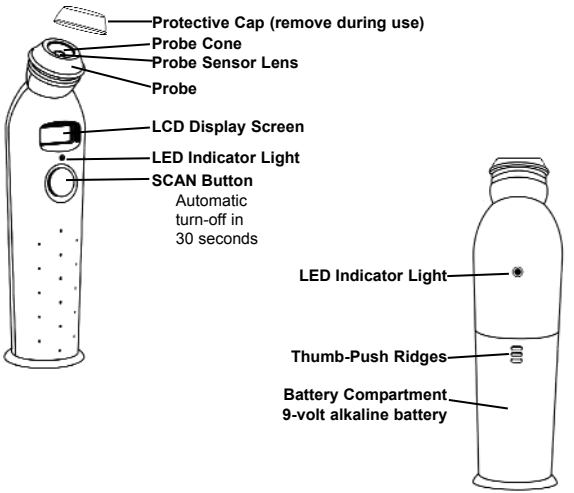
As you gently stroke the thermometer across the forehead crossing over the temporal artery, the sensor in its probe performs two processes:

First it scans like a video camera, capturing naturally emitted infrared heat from the arterial blood supply at about 1000 times per second, locking in the highest temperature it senses and;

Second, at the same time, a patented system measures the ambient temperature of the area where the temperature is being taken. The patented "arterial heat balance" (AHB) software then synthesizes the two separate readings to accurately determine and display body temperature.

As with any thermometer, taking temperatures properly is critical to obtaining accurate temperatures, so please read all instructions carefully and thoroughly before using this product.

Before Using, Familiarize Yourself with the Instrument



- To Scan: Depress the button. The instrument will continually scan for the highest temperature (peak) as long as the button is depressed.

- Beeping and LED flashing: Beep and LED flashing indicate a rise to a higher temperature, similar to a radar detector. Slow beeping indicates that the instrument is still scanning, but not finding any higher temperatures.

- Retain Reading: The reading will remain on the display for 30 seconds after the button is released.

- To Restart: Depress the button to restart. It is not necessary to wait until the display is clear, the thermometer will immediately begin a new scan each time the button is depressed.

Measuring TA Temperature

What you ***should*** know before using the TAT:

- Measure only the side of the head exposed to the environment. Anything covering the area to be measured (hair, hat, wig, bandages) would insulate the area, resulting in falsely high readings.
- Slide the thermometer straight across the forehead, not down the side of the face. Midline on the forehead, the TA is about a millimeter below the skin, whereas at the side of the face, the TA is much deeper, and measuring there would result in falsely low readings.
- When taking the temperature behind the ear lobe (if there is perspiration on the forehead, see pg 7), first push away any hair, exposing the area. Then, tuck the thermometer on the neck under the ear lobe, in the soft conical depression, (the place where perfume might be applied).
- Wait about 30 seconds before measuring the same person again to avoid excessive cooling of the skin.
- An infant is frequently swaddled in blankets and clothing covering the neck area. Unless visibly sweaty, one measurement at the TA area is typically all that is required. Should you feel the temperature is low, then push aside any clothing or blankets covering the neck area for ~30 seconds or so, and repeat the measurement on the neck behind the ear.

Factors that may affect measurement accuracy:

The patented AHB technology in your TemporalScanner actually makes two separate measurements (1) the temperature of the skin over the temporal artery, and (2) the temperature of the room. To determine the most accurate reading, it measures both temperatures some 1000 times a second as you sweep the TemporalScanner across the forehead. The AHB system then calculates how much the blood has cooled down during its journey from the heart to the skin over the temporal artery and makes allowance for this in the temperature it displays. The result is a highly accurate reading - delivered extremely fast and with no discomfort.

To ensure that the reading always reflects the body temperature accurately, you need to take account of the following factors which may affect an accurate reading.

Sweating:

When a fever resolves, your body may bring its temperature down by sweating.

The TemporalScanner detects this reduction in temperature immediately - long before a rectal thermometer can do so. However, sweating also causes extra cooling of the skin. As a result the reading given by the TemporalScanner may be low. You should therefore either wait until the sweating has stopped (wiping the forehead is not recommended, since the sweating immediately begins again), or use the following method, which has been clinically proven to provide accurate results.

1. Scan the temperature as normal, keeping the button depressed
2. Gently nestle the TemporalScanner on neck directly behind ear lobe
3. Release the button and read the temperature

Note: Normally, the artery behind the ear lobe does not provide a sufficiently accurate reading. However, this area is less affected by sweating than the forehead. In addition, during sweating, increased blood flow produces higher skin temperature, equivalent to TA, resulting in a good reflection of body temperature.

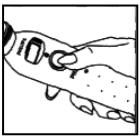
Environmental effects:

As part of its AHB system, the TemporalScanner measures the temperature of the surrounding environment. For this measurement to be accurate, it needs to have become acclimatised to the temperature of the room in which it is to be used. If it is taken from a cold room into a hot room, or vice versa, allow it to acclimate for at least 30 minutes before using it. Avoid holding the TemporalScanner by the head, as it will mistake the temperature of your hand for that of the room.

What else should I know?

If your child is agitated, or squirms away before you have completed your measurement, just keep the button depressed and you can continue the measurement without having to wait.

How to Take a Temperature



1. Remove protective cap before use. Be sure lens is clean. If not, clean with cotton swab dipped in alcohol and let dry. Hold the thermometer as shown.

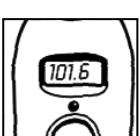
2. Gently position the probe flush (flat) on the center of the forehead, midway between the eyebrow and the hairline. Press and hold the SCAN button.

3. Lightly slide the thermometer across the forehead keeping the sensor flat and in contact with the skin until you reach the hairline.

➔ You will hear a beeping and a red light will blink to indicate a measurement is taking place.

➔ If perspiration is present, continue to hold button depressed, lift probe from forehead and touch the neck just behind the ear lobe.

4. Release the SCAN button and remove the thermometer from the head.



5. Read the temperature on the display. Thermometer will shut off automatically after 30 seconds. To turn thermometer off immediately, press and release the button quickly.

6. Replace the protective cap on thermometer to protect the sensor when not in use.

Clinical Temperature Information

Normal Body Temperature (BT)

Normal BT is not a single temperature, but a range of temperatures influenced by age, time of day, and measurement site. You can establish your family's normal ranges by taking a number of temperatures from each member during a day and keeping records of them. Many people may not have an elevated temperature even if they are ill. These include, but are not limited to, infants under 90 days old, people on steroids, antibiotics or antipyretics (acetaminophen, ibuprofen, aspirin), people with compromised immune systems (including the elderly and those having HIV/AIDS). Consult your doctor if you feel someone is ill even if their temperature is not elevated.

An elevated temperature or fever is often viewed as a danger sign. In fact, fever can be beneficial. It should be evaluated in the light of other physical symptoms. A doctor should be consulted in the following situations where fever is present: vomiting, diarrhea, changes in appetite, activity or breathing, or with children who are irritable, lethargic or unusually sleepy.

Normal Temporal Artery (TA) Temperature: The range of normal TA temperatures has been established by a large study by Dr. Keith Powell[5], for which he reports "After using the Temporal Scanner Infrared Thermometer to determine the range of normal temperatures in over 2300 infants and children (see table below from his study[6]) the staff in our 15 pediatric practices won't use any other thermometer. The Temporal Scanner is accurate, fast, non-invasive, and well tolerated by children of all ages." A temperature higher than those shown in the table is normally considered to be a fever, but consult your doctor for medical advice. For ages greater than 18 years, 100.1°F (37.8°C) should be used.

Age	Upper limit of normal temperature
0-2 months	100.7°F (38.1°C)
3-47 months	100.3°F (37.9°C)
4-9 years	100.1°F (37.8°C)
10-18 years	100.1°F (37.8°C)

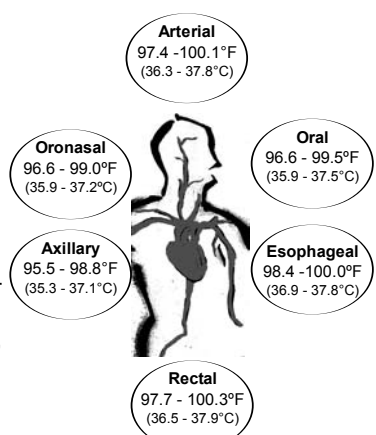
On a stable resting individual, temporal artery temperature is about the same as a rectal temperature, and approximately 0.8°F (0.4°C) higher than an optimum oral temperature. However, during fever episodes, the difference can be much higher, mainly because of the much greater speed of the TA compared to ear, oral, or rectal sites in responding to change in fever.

Normal Rectal and Oral Temperature: According to the American Academy of Pediatrics,[4] ordinarily, a rectal reading of 100° F (37.8°C) or less, or an oral reading of 99° F (37.2°C) or less, is considered normal, while higher readings indicate fever.

General Rule of Thumb: Rectal temperature is about 2°F (1°C) higher than underarm, about 1°F (0.5°C) higher than oral temperature.[7]

Expect the Differences: Arterial temperature measurement leads all other methods in identifying fever or falling of an elevated temperature, and is unaffected by activities of daily living. Accordingly, it will sometimes be different from other methods — *but accurate.*

Normal Body Temperature Ranges at Various Measurement Sites



Oral Temperature Artifacts:

Oral temperature can be misleading, and many individuals with fever can have a "normal" temperature.[8] Mouth breathing, rapid breathing, and hot or cold fluids are a few of the artifacts that can distort the reading, as can inability of the individual to cooperate. Accordingly, comparisons with TA may not be reliable.

Rectal Temperature Artifacts: Rectal temperature should only be considered as a good approximation of core temperature when the patient's thermal balance is stable,[9] and may be misleading after antipyretics, physical exercise, or other intervention that may change temperature quickly.

Axillary Temperature Artifacts: Based on strong evidence cited by the National Institutes for Health, *"axillary temperature is contraindicated in critically ill adults, and its use in the general patient population should be discouraged due to its unreliable correlation with core temperature and its poor reproducibility."* [10]

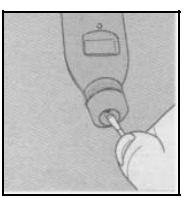
References:

1. Greene DS, Fleisher GR. Accuracy of a noninvasive temporal artery thermometer for use in infants, *Arch Pediatr Med* 2001 Mar;155(3):376-381
2. Schuh S, Komar L, Stephens D, Chu L, Read S, Allen U. Comparison of the arterial heat balance temporal artery, aural and rectal thermometry in children in the emergency department. Presented at the University of Toronto Emergency Medicine Research Academics Day, October 30, 2001.
3. Studies on file at Exergen. Published or presented studies available from Exergen.
4. *Caring for Baby and Young Child: Birth to Age 5*, American Academy of Pediatrics, Bantam 1999.
5. Keith R. Powell, M.D., Dr. Noah Miller Chair of Pediatrics, Children's Hospital Medical Center of Akron, and Professor and Chair of Pediatrics, Northeastern Ohio Universities College of Medicine.
6. Roy S, Powell K, Gerson LW. Non-invasive temporal artery temperature (TAT) measurements in healthy infants, children, and adolescents. European Society for Pediatric Infectious Diseases, 2002 Conference, Vilnius, Lithuania, May 29-31, 2002.
7. Kuzucu EY. Measurement of temperature. *Int Anesthesiol Clin,* 3(3):435-49, May, 1965
8. Tandberg D, Sklar D. Effect of tachypnea on the estimation of body temperature by an oral thermometer. *NE J Med*, 308, 945-46,1983
9. Houdas Y, et al. Human body temperature. Ch 5, p89, Plenum Press, 1982, USA, UK
10. O'Grady NP, Barie PS, Bartlett JG, et al. Practice guidelines for evaluating new fever in critically ill adult patients. Task Force of the Society of Critical Care Medicine and the Infectious Diseases Society of America. *Clin Infect Dis* 1998 May:26(5):1042-59

Cleaning the Instrument

The TemporalScanner is an optical instrument. Like a camera or eye glasses, a dirty lens will distort the view. If the thermometer is unable to see the heat clearly, it will be unable to measure it accurately, resulting in low readings.

- Probe lens and cone should be shiny clean, if not, wipe with a small cloth or swab moistened with alcohol.

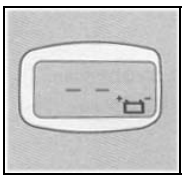


- Hold upside-down to prevent excess moisture from entering the sensor area. It will not harm the sensor, but if it becomes too wet, you will be unable to take a temperature until it dries.

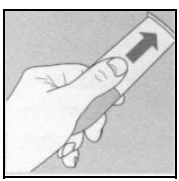
- Thermometer case can be cleaned with any hospital approved disinfectant, alcohol, even bleach solutions. Avoid gritty, abrasive cleaners as they can scratch the thermometer.

- Do not hold the TemporalScanner under the faucet or submerge in water. It is not water-proof.

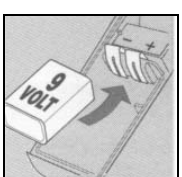
Changing the Battery



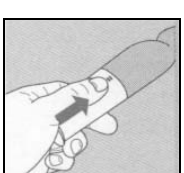
Blinking battery icon with temperature displayed: battery is low but will still operate correctly. Replace soon.
Blinking battery icon with 2 dashes: not enough energy in the battery to measure correct temperature. Replace battery.



Remove the battery compartment door by pushing down on the ridges with your thumb, and pushing away as indicated.



Insert an alkaline 9-volt battery as illustrated, with the positive (small terminal) always on the right.



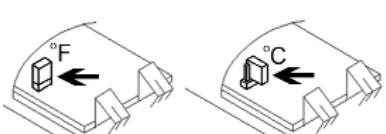
Replace the battery compartment door as indicated, with a push of your thumb on the ridges.

Display Messages

SCN	A flickering Scn on display is visible during measurement. At completion, releasing the button will display and lock temperature on the screen for 30 seconds.
KI	The target temperature measured is higher than 107.6°F (42°C).
L0	The target temperature measured is lower than 60°F (15.5°C).
KI .A	Temperature of the thermometer is higher than 104°F (40°C). Let the instrument acclimatize for about 30 minutes in a cooler area in which it will be used.
L0 .A	The temperature of the thermometer is lower than 60°F (15.5°C). Let instrument acclimatize for about 30 minutes in a warmer area in which it will be used.
ERR	EMI/RFI (like static on a radio) protection is preventing a temperature from being taken. Wait a minute and you should be able to proceed. If not, reset by removing and replacing the battery. Be sure battery is tightly connected. Call Customer Service if error message reappears.

°C/°F Conversion

Remove the battery cover and battery. Remove the clip shown by the arrow. Replace the clip in either the °C position or the °F position shown by the diagram. Replace battery and battery cover.



Product Specifications

Clinical Accuracy	Meets ASTM E1965-98 and EN60601-1 standards for electronic and radiation thermometers to the extent applicable to thermometers which measure the surface of the skin over the temporal artery.
Regulatory Approvals	CE Mark to -0197, TUV, Declaration of Conformity-ISO 9003/08.94, NIST certifiable traceable calibrations, UL listed.
EMI/RFI Protection	Error message displayed
Calibration Protection	Error message displayed
Temperature Range	15.5 to 42°C (60 to 107.6°F)
Operating Environment	15.5 to 40°C (60 to 104°F)
Resolution	0.1°C or °F
Response Time	Approximately 0.04 second
Time Displayed on Screen	30 seconds before automatic shutdown
Battery Life	Approximately 7,500 readings
Size	7.0 in x 1.75 in x 1.25 in (17.8 cm x 4.45 cm x 3.18 cm)
Weight	4.5 oz (130 grams) incl batt
Display Type	High contrast LCD
Construction Method	Impact resistant casing, hermetically sealed sensing system
Warranty	1 Year
Laboratory Error:	See below
Storage Range:	-4°F to 122°F (-20°C to 50°C)
Patents	Protected by the following US patents: 4636091, 5012813, 5199436, 5653238, 5874736, 6045257, 6047205, 6056435, 6292685, 6299347, 6319206, 6402371 Other US and foreign patents pending.

ASTM laboratory accuracy requirements in the display range of 37° to 39°C (98 to102°F) for IR thermometers is +/-0.2°C(+/-0.4°F) whereas for mercury-in-glass and electronic thermometers, the requirement per ASTM standards E667-86 and E1112 is +/-0.1°C (+/-0.2°F).
*Full responsibility for this product meeting applicable portions of this standard is assumed by Exergen Corporation, Watertown, MA 02472

One Year Warranty

Exergen Corporation warrants each new Exergen TemporalScanner 2000C (except battery) against defects in materials or workmanship for a period of one year from the date of purchase, and agrees to repair or replace any defective product without charge.

IMPORTANT: This warranty does not cover damage resulting from accident, misuse or abuse, lack of reasonable care, the affixing of any attachment not provided with the product or loss of parts or subjecting the product to any but the specified battery.* Use of unauthorized replacement parts will void this warranty.

Exergen Corporation will not pay for warranty service performed by a non-authorized repair service and will not reimburse the customer for damage resulting from warranty service performed by a non-authorized repair service. No responsibility is assumed for any special, incidental or consequential damages.

In order to obtain warranty service, simply call Exergen Corporation Customer Service, 617-923-9900, for a Return Material Authorization number (RMA). Then send the product, postage or shipping prepaid, to Exergen in accordance with the instructions given with the RMA number. It is suggested that for your protection, you ship the product, insurance prepaid. Damage occurring during shipment is not covered by this warranty.

NOTE: No other warranty, written or verbal, is authorized by Exergen Corporation. This warranty gives you specific legal rights and you may also have other rights which vary from state to state. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above exclusion and limitations may not apply to you.

*Read enclosed instructions carefully.

Made in U.S.A.

LISTED

This symbol on the product's nameplate means it is listed by Underwriters' Laboratories, Inc.

CE 0197

Developed, designed, and manufactured by Exergen Corporation in the USA

EXERGEN CORPORATION
WATERTOWN, MA 02472

www.quickmedical.com/exergen

© 2002 Exergen Corporation. All rights reserved.

P/N 818541 Rev 4